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1 CLAIMS

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3 1. A method for improving the efficacy of drug
4 trials, the method comprising the step of
5 screening samples from potential participants for
6 the genetic basis of Gilbert's Syndrome and
7 eliminating or including potential participants in
8 a drug trial in the knowledge of them possessing
9 or not possessing the genetic basis of Gilbert's
10 Syndrome.

11

12 2. A method as claimed in claim 1 comprising the
13 steps of:

14

15 a) taking a sample from each potential
16 participant in a drug trial,

17

18 b) screening the samples for the genetic basis
19 of Gilbert's Syndrome,

20

21 c) identifying participants having the genetic
22 basis of Gilbert's Syndrome, and

23

24 d) proceeding with drugs trials in the knowledge
25 of participants possessing or not possessing
26 the genetic basis of Gilbert's Syndrome.

27

28 3 A method as claimed in claim 1 or 2 wherein the
29 sample is chosen from blood, buccal smear or any
30 other sample containing DNA from the potential
31 participants.

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33 4. A method as claimed in any of the preceding claims
34 further comprising the step of eliminating
35 participants having the genetic basis of Gilbert's
36 Syndrome from a drugs trial.

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- 1 5. A method as claimed in any of claims 1 to 3
2 wherein the method comprises the further step of
3 selecting only participants having genetic basis
4 for Gilbert's Syndrome for a drugs trial.
5
- 6 6. A method as claimed in any of claims 1 to 3
7 further comprising the step of interpreting the
8 results of the drugs trial in the knowledge that
9 certain participants have Gilbert's Syndrome.
10
- 11 7. A method as claimed in any of the preceding claims
12 wherein the method comprises the steps of:
13
- 14 a) isolating DNA from each sample,
15
- 16 b) amplifying the DNA inner region indicating
17 the genetic basis for Gilbert's Syndrome,
18
- 19 c) isolating amplified DNA fragments, and
20
- 21 d) identifying individuals having the genetic
22 basis of Gilbert's Syndrome.
23
- 24 8. A method as claimed in any of the preceding claims
25 wherein the DNA is amplified using the polymerase
26 chain reaction (PCR) using a radioactively
27 labelled pair of nucleotide primers.
28
- 29 10. A method as claimed in any of claims 7 to 9
30 wherein the DNA region indicating the genetic
31 basis of Gilbert's Syndrome is the gene encoding
32 UDP-glucuronosyltransferase (UGT).
33
- 34 11. A method as claimed in any of claims 7 to 10
35 wherein the DNA to be amplified is in an upstream
36 promoter region of the UGT 1*1 exon 1.

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- 1 12. A method as claimed in any of claims 7 to 11
2 wherein the DNA to be amplified includes the
3 regions between -35 and -55 nucleotides at the 5'
4 end of UGT 1*1 exon.
5
- 6 13. A kit for screening individuals participation in
7 drug trials, the kit comprising primers for
8 amplifying DNA in the region of the genome
9 indicating the genetic basis of Gilbert's
10 Syndrome.
11
- 12 14. Primers for use in a method as claimed in any of
13 the preceding claims including primer pairs, AB or
14 CD as follows:
15
- 16 A/B (A, 5'-AAGTGAAGTCCCTGCTACCTT-3',
17 B, 5'-CCACTGGGATCAACAGTATCT-3') or
18 C/D (C, 5'-GTCACGTGACACAGTCAAAC-3';
19 D 5'-TTTGCTCCTGCCAGAGGTT-3').

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